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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,151	01/17/2001	Gilbert R. Gonzales	UNSP/ 04	6299

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EXAMINER	
RAMANA, ANURADHA	
ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/765,151	GONZALES ET AL.	
	Examiner	Art Unit	
	Anu Ramana	3732	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 12-23 and 25-27* is/are rejected.

7)☒ Claim(s) *10,11 and 24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 15 is objected to because of the following informalities. In line 6, "said subject" should be "said patient" to correct a minor typographical error. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Singh et al. (US 5,458,879).

Singh et al. disclose an oral composition (chewable tablet or liquid) containing a coloring agent (FD&C Red #40) or marker wherein the composition coats and adheres to the throat (pharyngeal) and mucous membranes (col. 1, lines 55-65, col. 5, lines 65-67, col. 6, lines 1-10 and lines 55-58 and col. 9, example III). Visible coloration of the mucous membranes is an inherent property of a coloring agent such as FD&C Red #40.

Regarding claim 20, the half-life of the ingested marker is "comparable" to the half-life of the composition in the human system since the coloration caused by a dye such as FD&C Red #40 is not permanent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rittenburg et al. (US 6,068,981) in view of Singh et al.

Rittenburg et al. disclose a method of monitoring oral administration of pharmaceutical compositions in humans to ensure compliance to a therapeutic regimen wherein the orally administrable composition has a marker or detectable compound that passes into a tissue of the patient and can be identified by color, fluorescence and spectroscopic methods (col. 1, lines 5-36, lines 48-60, col. 2, lines 20-24 and lines 65-67, col. 3, lines 1-19 and lines 26-32 and col. 6, lines 5-9).

Coloration of specific tissues is a function of the composition ingested by the patient. Thus, contact coloration of the oral/pharyngeal cavity would result if a patient ingests a composition such as one taught by Singh et al.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized presence or absence of contact coloration of the oral/pharyngeal cavity to monitor compliance of a patient in ingesting a composition such as taught by Singh et al. as part of a therapeutic regimen.

Regarding claim 3, a placebo is well known in drug trials wherein the patient is told that the "placebo" is a drug and is treated like a drug. Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a marker combined with a placebo in a drug trial for introducing the "placebo" as an actual drug.

Regarding claims 5 and 6, the method steps are inherent to the type of dye in the composition being orally administered to a patient. For e.g., if a fluorescent dye is present in the composition, then fluorescent light with an optimal wavelength would be utilized to detect the coloration in the tissue.

Regarding claim 6, Rittenburg et al. disclose the claimed invention except for the wavelength of the fluorescent light utilized to detect tissue coloration. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized violet-blue light having a wavelength in a range from about 430 nm to about 490 nm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).*

Regarding claim 8, the use of carmine red in orally administered pharmaceutical compositions is well known (see Pather et al, (US 6,200,604)). Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the method of Rittenburg et al. to detect tissue coloration caused by consumption of a orally administered pharmaceutical composition containing carmine red dye.

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rittenburg et al. in view of Blasé et al. (US 5,272,137).

See previous discussion of the Rittenburg et al. reference.

Coloration of specific tissues is a function of the composition ingested by the patient. Thus, contact coloration of the oral/pharyngeal cavity would result if a patient ingests a composition with multiple dyes or markers such as one taught by Blasé et al.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized presence or absence of contact coloration of the oral cavity to monitor compliance of a patient in ingesting a composition with multiple markers such as one taught by Blase et al. as part of a therapeutic regimen. Further, different contact coloration is an inherent property of different dyes.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al. in view of Pather et al. (US 6,200,604).

Singh et al. do not disclose that carmine red.

The use of dyes such as carmine red and FD&C dyes in oral compositions is well known. Pather et al. teach the use of carmine, beta-carotene and FD&C dyes in orally ingested compositions (col. 5, lines 1-6).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected carmine or FD&C dyes as the dye in the marker composition of Singh et al. due to their suitability for oral consumption as taught by Pather et al.

Claims 23 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al. in view of Blasé et al.

Singh et al. do not disclose multiple markers.

Blasé et al. disclose multiple makers in a pharmaceutical composition to provide an appealing color (col. 6, lines 3-8 and col. 7, lines 32-34).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided multiple markers Singh et al. pharmaceutical composition, as taught by Blasé et al., to impart an appealing color to the Singh et al. pharmaceutical composition.

Regarding claims 25-27, different contact coloration and whether the color is visible to the naked eye or under fluorescent light is dependent on the type of dye present in the composition.

Allowable Subject Matter

Claims 10, 11 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicants' arguments with respect to claims 1-27 in Paper No. 14 filed on February 20, 2004, have been considered. Applicants' arguments with respect to claims 1-9, 12-23 and 25-27 are moot in view of the new grounds of rejection in this office action.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR Anuradha Ramana
April 22, 2004

KEVIN SHAVER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700